IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: ARMODAFINIL PATENT LITIGATION	MDL Docket No. 1:10-md-2200-GMS
CEPHALON INC. and CEPHALON FRANCE, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 1:09-cv-954-GMS
CEPHALON INC. and CEPHALON FRANCE, Plaintiffs, v. WATSON LABORATORIES, INC., Defendant.	Civil Action No. 1:10-cv-7-GMS
CEPHALON INC. and CEPHALON FRANCE, Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 1:10-cv-55-GMS
CEPHALON INC. and CEPHALON FRANCE, Plaintiffs, v. LUPIN LIMITED, Defendant.	Civil Action No. 1:10-cv-210-GMS
CEPHALON INC. and CEPHALON FRANCE, Plaintiffs, v. APOTEX CORP. and APOTEX INC., Defendants.	Civil Action No. 1:10-cv-695-GMS Civil Action No. 1:10-cv-1078-GMS

DECLARATION OF SIMON BATES, PH.D.

I. Introduction

1. I have been retained by Cephalon Inc. and Cephalon France (collectively "Cephalon") in the above-referenced matter and provide this declaration in relation to Cephalon's proposed claim constructions. I considered the claims, specification and prosecution history of U.S. Patent No. 7,132,570 ("the '570 patent"), as well as my own experience and expertise.

II. Qualifications

2. I am currently an Associate Adjunct Professor in the Department of Industrial Pharmacy at Purdue University in West Lafayette, Indiana. I also am presently a Research Fellow at Triclinic Labs in West Lafayette, Indiana. Triclinic Labs is a leading provider of services in solid-state chemical development and materials analysis. My current interests are in the characterization of active pharmaceutical ingredients and formulated products in the solid state using a variety of state-of-the-art analytical techniques, including X-ray diffraction, Raman spectroscopy, and differential scanning calorimetry.

3. I obtained my Bachelor of Science in Applied Physics and Diploma of Applied Physics from the University of Hull in the United Kingdom in 1981. Thereafter, I obtained my Ph.D. degree in Applied Physics in 1985 from the University of Hull in the United Kingdom and the Institute Laue Langevin in France.

4. I have close to 30 years experience working with solid state characterization, and in particular, X-ray and neutron diffraction characterization of the solid state. For the last 9 years, I have been working on characterization and modeling of pharmaceutical materials including both active pharmaceutical ingredients and drug product systems.

5. Since receiving my Ph.D. in Applied Physics, I worked within the Analytical X-ray Instrumentation industry holding positions of Product Manager at Philips Analytical (PanAlytical) and Kratos (Shimadzu), and VP of Science at Bede Scientific. Before moving to Triclinic Labs, I worked at SSCI as a Research Fellow and a Principal at Aptuit Consulting.

6. My work on pharmaceutical systems at SSCI/Aptuit has resulted in 13 peer-reviewed publications and more than 10 patent applications, a number of which focus on X-ray diffraction and polymorphs.

7. In addition to X-ray and neutron diffraction, my expertise includes computational modeling of molecular systems, computational methods for infrared spectroscopy, thermal analysis, and chemometrics. I have over 40 peer-reviewed international publications and has been an invited speaker at many scientific conferences.

8. My background and qualifications are more fully set out in my curriculum vitae, which is included with this declaration as Exhibit A. I have also listed in Exhibit A the cases in which I have testified during the past four years.

III. Summary of Opinion

9. The armodafinil polymorph designated "Form III" in the '570 patent is a mixture of Form I (Form A) and Form IV (Form B) armodafinil polymorphs and not a single distinct polymorph of its own. My conclusion is based on all of the peaks in the Form III diffraction pattern corresponding to peaks in the diffraction patterns obtained for Form I and Form IV, and is further confirmed by the evidence in the '570 patent file history showing that mixtures of Form I and Form IV do occur.

IV. X-ray Diffraction Patterns of Form I, Form IV, and "Form III"

10. The Blomsma Declaration from the file history of the '570 patent provides the X-ray diffraction pattern of armodafinil crystalline "Form A" obtained using copper radiation. (JX

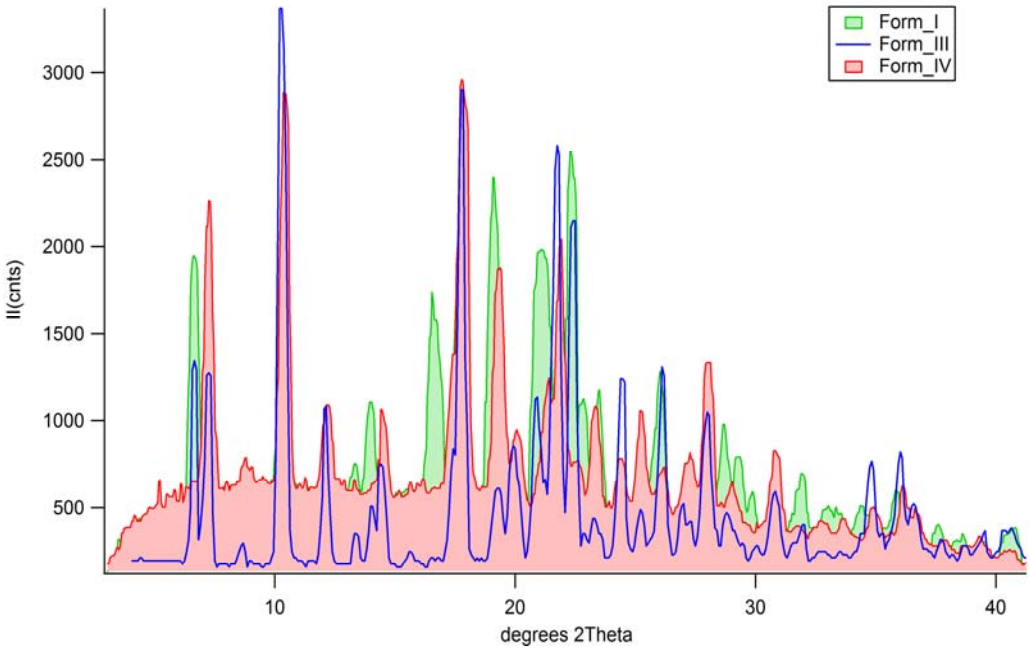
6 at JA100.) Form A corresponds to Form I of the '570 patent, and I will refer to it using the '570 patent Form I designation. (JX 1 at JA 18-19, col. 2:48-3:10; Mallamo Decl. ¶ 16, JX 7 at JA107.)

11. The Blomsma Declaration also includes the X-ray diffraction pattern of armodafinil crystalline "Form B" obtained using copper radiation. (JX 6 at JA101.) Comparison of this diffraction pattern with the diffraction pattern of Form IV shown in Figure 11 of the '570 patent (JX 1 at JA12) and table at col. 9:14-34 (JX 1 at JA22) indicates that Form B corresponds to the polymorph designated Form IV in the '570 patent, and I will refer to the polymorph as Form IV for consistency with the patent.

12. The Form III X-ray diffraction pattern obtained using chromium radiation is shown in Figure 10 of the '570 patent. (JX 1 at JA11.)

13. In order to compare the "Form III" diffraction pattern with the patterns obtained for Form I and Form IV, I re-scaled the Form III diffraction pattern obtained using chromium radiation into the equivalent copper-radiation diffraction pattern. I did this using the scanning and digitization software UN-SCAN-IT v. 6.0 and graphics software IGOR PRO v. 6.2.2.2, which converted the 2-theta diffraction angle measured with chromium into the corresponding angles for copper according to the Bragg equation.

14. I then overlaid the X-ray diffraction patterns for Forms I and IV from the Blomsma Declaration and the re-scaled Form III X-ray diffraction pattern from Figure 10 of the '570 patent. The resulting graphic is shown below and in Exhibit B.



In the data above, the intensity of the Form III diffraction pattern was scaled by a factor of 2.2 so that the peak heights are comparable to those in the Form I and Form IV diffraction patterns. In addition, the Form III diffraction pattern was shifted positive 0.2° 2 theta, consistent with the variance disclosed in the '570 patent (JX 1 at JA31, col. 27:6-9) and my experience in x-ray diffraction measurement and digitized data.

15. A visual inspection of the graphic above reveals that the peaks in the Form III X-ray diffraction pattern (blue curve) correspond to peaks in either the Form I diffraction pattern (green curve) or Form IV diffraction pattern (red curve). For example, the tall peak in the Form III pattern near 10° 2 theta corresponds to a peak in Form IV. It is not expected that the heights (intensities) of the peaks in the different patterns will necessarily be the same. This is due to well-known effects, such as (1) preferred orientation, (2) differences in X-ray optics of the instruments used in collecting the X-ray diffraction patterns, and (3) comparing a mixture to pure materials.

16. The Form III interplanar spacings tabulated in the ’570 patent for Form III likewise correspond to interplanar spacing values for either Form I or Form IV that are disclosed in the ’570 patent or apparent from the above patterns:

Form III	Form I	Form IV
13.40	✓	
12.28		✓
8.54	✓	✓
7.32		✓
6.17		✓
5.11		✓
5.01	✓	✓
4.48		✓
4.44	✓	
4.27	✓	✓
4.19	✓	✓
4.10		✓
4.02	✓	
3.97	✓	
3.66		✓
3.42	✓	✓
3.20		✓
2.91		✓
2.58		✓

To be clear, the last 2 interplanar spacing values identified for Form III in the '570 patent, *i.e.*, 2.91 and 2.58 Å, are not found in the '570 patent data tables. However, they are evident in the diffraction pattern for Form IV. More specifically, these interplanar spacings correspond to 2 theta values of 30.7° and 34.7°, respectively, when using copper radiation (λ = 1.54 Å). These peaks are clearly evident in the Form IV diffraction pattern above.

17. Having been able to assign the peaks in the Form III diffraction pattern to either Form I or Form IV, it is my opinion that Form III is not a distinct armodafinil polymorph but is instead a mixture of armodafinil Forms I and IV.

18. It is not unusual to obtain a mixture of polymorphs. Indeed, Dr. Mallamo reports obtaining a mixture of Forms I and IV. (*See* Mallamo Decl., JX 7 at JA106 (¶ 14), JA121, JA124.)

I declare under the penalties of perjury that the foregoing statements are true and correct to the best of my knowledge and belief.

Date: June 15th 2011

Simon Bates, Ph.D.